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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,117	07/31/2003	Hilda Elizabeth Smith	2183-6055US	5350

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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
06/16/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTOMail@traskbritt.com

Office Action Summary	Application No.	Applicant(s)	
	10/632,117	SMITH, HILDA ELIZABETH	
	Examiner	Art Unit	
	JaNa Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6,7,9 and 21-29* is/are pending in the application.

4a) Of the above claim(s) *1,6,7,9,28 and 29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/23/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 23, 2009 has been entered.

Claim Status

2. Claims 2-5, 8 and 10-20 are cancelled. Claims 1, 6-7, 9 and 28-29 are withdrawn from consideration. Claims 21-27 are under consideration in this office action.

Election/Restrictions

3. Previously submitted claims 28-29 directed to an invention that is independent or distinct from the invention originally claimed. Applicants argue that claim 29 is not directed to a sequence comprising SEQ ID NO: 37, has a means for hybridizing to SEQ ID NO: 37; therefore is directed to applicants previously elected subject matter. However, it is the Office's position that claims 28-29 are directed to an independent invention. Accordingly, claims 28-29 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. The requirement is still deemed proper and is therefore made FINAL.

Response to Arguments

4. Applicant's arguments filed March 23, 2009 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The written description rejection of claims 21-27 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for reasons already of record.

The claims are drawn to an isolated or recombinant nucleic acid molecule comprising a nucleotide sequence of *Streptococcus suis* origin wherein the nucleotide sequence comprises a contiguous sequence which hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37 at 65°C in a buffer having 0.5 M sodium phosphate, 1 mM EDTA, and 7% sodium dodecyl sulphate at a pH of 7.2, wherein the nucleic acid molecule remains hybridized after washing twice with a buffer containing 40 mM sodium phosphate (pH 7.2), 1 mM EDTA and 5% sodium dodecyl sulphate for 30 minutes at 65°C and; washing twice with a buffer containing 40 mM sodium phosphate (pH 7.2), 1 mM EDTA and 1% sodium dodecyl sulphate for 30 minutes at 65°C and wherein the complement of the nucleotide sequence encodes for a portion of a fibronectin-/fibrinogen-binding protein (FBPS) of *Streptococcus suis.*

Applicants assert that paragraph [0105] states that SEQ ID NO:37 was used as a probe to identify chromosomal fragments of *S. suis* serotype 2 containing FBPS sequences and therefore necessarily includes a complementary sequence that hybridizes to SEQ ID NO:37 in accordance with the claims. However the issue is not whether the is written description of a nucleotide sequence of *S. suis* origin wherein the nucleotide sequence comprises a contiguous sequence which hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37; rather the issue is whether there is adequate written description support for the complement of the nucleotide sequence which hybridizes to SEQ ID NO:37 and encodes for a portion of a FBPS of *S. suis.*

Applicants submit that complement of the of the described nucleic acid sequence that hybridizes to the full length of nucleotides 89-263 of SEQ ID NO:37 under the recited conditions would have a complement that necessarily includes a nucleotide sequence that encodes for a portion of a FBPS of *S. suis.* However it is the Office's position that applicants have not provided any written description for that complement.

Applicants submit that because the described nucleotide sequence, or fragment including the claimed nucleotide sequence, is complementary to SEQ ID NO:37 a complement of a claimed nucleic acid sequence would necessarily include nucleotides 89-263 of SEQ ID NO:37. Contrary to Applicants assertions, the specification does not describe any FBPS of *S. suis* that are encoded by the complement of a nucleotide sequence that hybridizes with SEQ ID NO:37 under the recited conditions. It is well known in the art that DNA that hybridizes to the DNA sequence that encodes a protein

is known as complementary DNA. "Complementary" is routinely used in the art to describe the opposite (complement) strand of a given DNA sequence; however the claim reads upon an isolated or recombinant nucleic acid molecule comprising a *S. suis* nucleotide sequence where the sequence hybridizes to SEQ ID NO:37 and the complement of the nucleotide sequences encodes for a portion of a portion of FBPS.

Applicants argument that nucleotides 89-263 of SEQ ID NO:37 encode for a portion of a FBPS of *S. suis* thus the sequence's complement would necessarily include a nucleotide sequence that encodes for a portion of a FBPS of *S. suis* is not persuasive. It is well known that antisense sequences do not encode products related to the sense strand, for example, the 5'- 3' directionality is reversed, and therefore each codon triplets is read in the reverse orientation (encoding a different amino acid in most instances) and the N and C terminal of the encoded product is reversed. Furthermore, there is no description of the complement of the nucleotide sequence which hybridizes to SEQ ID NO:37 under the instantly claimed conditions encodes for a portion of a FBPS of *S. suis*.

Applicants urge that because of the "highly stringent conditions" claimed, the specification's described 5kb fragment and pFBPS7-46 would necessarily include a contiguous sequence that hybridizes to the full length of nucleotides 89-263 of SEQ ID NO:37 thus, the specification describes the claimed nucleic acid structurally, functionally, and by relevant characteristics. However, it is the position of the Office that the specification describes the nucleotide sequences of SEQ ID NO:37 and sequences which hybridize to SEQ ID NO:37; however that is not equivalent to a description of the

complement to the hybridizing strand which encodes a portion of FBPS. There is no disclosure of a nucleic acid molecule that hybridizes to SEQ ID NO:37 wherein the complement of the hybridizing nucleotide sequence encodes for a portion of a FBPS of *S. suis.*

Applicant has not provided any guidance or working examples which would lead one of skill in the art to predict that the nucleotide sequence of *S. suis* origin wherein the nucleotide sequence comprises a contiguous sequence which hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37 under the instantly claimed conditions and wherein the complement of the nucleotide sequence encodes for a portion of a FBPS of *S. suis* does, in fact, encode protein product (e.g. start sequences, methionine codon, a substantial open reading frame, stop and other termination signals). Furthermore, one of skill in the art would not predict that such a product would be structurally or functionally related to the protein with the sequence of SEQ ID NO:37, and applicant has not provided any potential means of using such an unrelated protein product, or any description of the structure or function of such a product.

Applicant respectfully notes that the claims are not directed to "any" nucleic acid sequence that hybridizes to or complements SEQ ID NO:37, but rather to those specific nucleic acid sequences that hybridize to or complement nucleotides 89-263 of SEQ ID NO:37 and whose complement encodes for a portion of a FBPS of *S. suis* as evidenced by (Exhibit A), the predicted FBPS protein submitted to GenBank as AF438159 [referenced in [0102] of the Specification], and a homology search on the sequence of

the FBPS protein (Exhibit C) suggest that any potential nucleic acid sequences that hybridize under the recited conditions would encode for a FBPS of *S. suis.* However the issue is not whether SEQ ID NO:37 would encode a portion of a FBPS of *S. suis* origin. And it is noted that none of the exhibits address whether the nucleotide sequence which hybridizes to SEQ ID NO:37 has a complement that encodes for a portion of a FBPS of *S. suis*. Therefore Applicants exhibits are not persuasive.

Applicants point to the homology search in Exhibit C and suggest that proteins with as low as fifty percent (50%) homology to the FBPS proteins of S. *suis are* FBPS proteins. Applicants submit that these homologous proteins are not from *S. suis,* but from other Streptococcus strains. Therefore it appears that Applicants have failed to provide support for an isolated or recombinant nucleic acid molecule comprising a nucleotide sequence of *S. suis* origin wherein the complement of the nucleotide sequence encodes for a portion of a FBPS of *S. suis.* None of the exhibits provide any written description support for a complement of the hybridizing strand that encodes a portion of a FBPS from *S. suis*. Moreover, the homology search failed to provide written description support for an isolated or recombinant nucleic acid molecule comprising a nucleotide sequence of *S. suis* origin.

Finally, Applicant submits that in view of the evidence of record and the remarks presented herein, the Specification adequately describes the claimed nucleic acid sequence and that the complement of the claimed nucleic acid sequence encodes for a portion of FBPS. The specification does not indicate that any nucleic acids that hybridize to SEQ ID NO: 37 under “highly stringent” conditions and has a complement

that encodes a FBPS of *S. suis.* Because hybridization under highly stringent conditions requires a high degree of structural complementarity, nucleic acids that hybridize to SEQ ID NO: 37 must share many nucleotides in common with SEQ ID NO: 37. The disclosure of SEQ ID NO: 37 combined with the knowledge in the art regarding hybridization would put one in possession of the genus of nucleic acids that would hybridize under stringent conditions to SEQ ID NO: 37. However, without a recognized correlation between structure and function, those of ordinary skill in the art would not be able to identify without further testing the complement of the nucleotide sequence that encodes for a portion of a FBPS of *S. suis* wherein the nucleotide sequence comprises which hybridizes to SEQ ID NO:37.

Thus, those of ordinary skill in the art would not consider the applicant to have been in possession of the claimed genus of an isolated or recombinant nucleic acid molecule. Therefore the specification fails to satisfy the written description requirement of 35 U.S.C.112, first paragraph, with respect to the full scope of claims 21-27. Accordingly, Applicants arguments have not been found persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. The new matter rejection of claims 21-27 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for reasons already of record.

The rejection is on the grounds that neither the specification nor originally presented claims provides support for an isolated or recombinant nucleic acid molecule comprising a nucleotide sequence of *S. suis* origin wherein the nucleotide sequence comprises a contiguous sequence which hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37 at 65°C in a buffer having 0.5 M sodium phosphate, 1 mM EDTA, and 7% sodium dodecyl sulphate at a pH of 7.2, wherein the nucleic acid molecule remains hybridized after washing twice with a buffer containing 40 mM sodium phosphate (pH 7.2), 1 mM EDTA and 5% sodium dodecyl sulphate for 30 minutes at 65°C and; washing twice with a buffer containing 40 mM sodium phosphate (pH 7.2), 1 mM EDTA and 1% sodium dodecyl sulphate for 30 minutes at 65°C and wherein the complement of the nucleotide sequence encodes for a portion of a FBPS of *S. suis.*

Applicants' point to paragraph [0082] for support in the specification which expressly describes the hybridization conditions. However the new matter rejection is based on the grounds that for an isolated or recombinant nucleic acid molecule comprising a nucleotide sequence of *S. suis* origin wherein the nucleotide sequence comprises a contiguous sequence which hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37 under the instantly recited

hybridization conditions wherein the complement of the nucleotide sequence encodes for a portion of a FBPS of *S. suis.*

Applicants also point to paragraphs [0105-0106] as providing a more than adequate disclosure for an isolated or recombinant nucleotide sequence that hybridizes to full length of nucleotides 89-263 SEQ ID NO:37. Applicant respectfully asserts that, at the very least, the specification inherently discloses "a nucleotide sequence comprising a contiguous sequence that hybridizes to the full length of nucleotides 89-263 of SEQ ID NO:37. However, Applicant is reminded that the claims are not just drawn to a nucleotide sequence comprising a contiguous sequence that hybridizes to the full length of nucleotides 89-263 of SEQ ID NO:37; rather the claims are drawn to a nucleic acid molecule wherein the complement of the hybridizing nucleotide sequence encodes for a portion of a FBPS of *S. suis.* Applicants' have not provided support for the complement.

Applicants assert that the inherent properties are present and inherently disclosed. However the "inherent properties" which Applicants are asserting relate to SEQ ID NO:37 and the hybridizing sequence. There appears to be no teaching of an isolated or recombinant nucleotide sequence comprises a contiguous sequence which hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37 and wherein the complement of the nucleotide sequence encodes for a portion FBPS of *S. suis.* Furthermore, there is no teaching of the contiguous sequence hybridizing to the full length of nucleotides 89-263. Applicants' have not specifically pointed to teaching of the contiguous sequence hybridizing to the full length of nucleotides 89-263 of SEQ ID NO:37. Therefore, it appears that the entire specification

appears to fail to recite support for the newly recited isolated or recombinant nucleotide sequence.

Despite applicants' assertions, there appears that there is no support in the specification or the claims. Therefore, applicants must specifically point to page and line number support for the identity an isolated or recombinant nucleic acid molecule comprising wherein the nucleotide sequence comprises a contiguous sequence which hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37 and wherein the complement of the nucleotide sequence encodes for a portion FBPS of *S. suis* as recited by the claims. Therefore, applicants' arguments are not persuasive and the rejection is maintained.

Conclusion

7. No claims allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Robert Mondesi, can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JaNa Hines/
Examiner, Art Unit 1645

/Mark Navarro/

Primary Examiner, Art Unit 1645